

REMARKS

The Office action makes reference on page 1 to a communication filed on 22 May 2006. Applicants' attorney did not file this communication and can find no such communication in the PAIR document chronology for this case. It is respectfully requested that applicants be provided with a copy of this communication.

The Examiner has noted a typographical error in Claim 5 and an inconsistency in paragraph lettering in a number of other claims. These informalities have been corrected in the above amendments to the claims.

Claims 1-2, 4-5, 14-16, 18-19, 38-40 and 44-47 were rejected under 35 U.S.C. §102(e) as being anticipated by US Pat. 6,535,714 (Melker et al.) Claim 1 describes a method for providing instruction on the use of a medical device to a user computer, the method comprising a) receiving a request for instruction on the use of the medical device over a network, the request originating from the user computer; b) providing a first graphical user interface having a list of instructional topics associated with the medical device to the user computer in response to the request; c) providing a second graphical user interface having a list of instructional sub-topics associated with an item on the list of instructional topics to the user computer in response to receiving a request for the item on the list of instructional topics from the user computer; d) providing a plurality of instructional graphical user interfaces having instructions pertaining to an item on the list of instructional sub-topics to the user computer in response to receiving a request for the item on the list of the instructional sub-topics from the user computer, at

least one of the first, second and plurality of instructional graphical user interfaces including at least one interactive simulation object with which interaction simulates operating controls or device instruments of the medical device; and e)generating a feedback in response to interacting with the interactive simulation object indicating (i) whether a particular interaction is appropriate under given conditions; and (ii) the correctness on the use of the medical device. The method of this invention provides a user with a list of topics associated with a medical device which have sub-topics that enable the user to obtain interactive instruction on a specific aspect of the medical device. The user is not restricted to only generalized instruction on the overall operation and use of the medical device, but can focus specifically on a sub-topic aspect of interest for instruction. Melker et al., like other citations in this case such as Ramshaw et al., have only a single level of overall instruction as exemplified by the Main Menu in FIG. 3 of the Melker et al. patent. The Examiner attempts to show both topics and sub-topics in Melker et al. by pointing first to Fig. 3 and col. 3, lines 12 -20 for the topics, then to col. 6, lines 48-51 for the subtopics. However both of these references are to the same thing, the Main Menu of Fig. 3. The first five topics of the Main Menu are lessons on the science and overall operation of the medical device. It is only the sixth topic, the Patient Management Exercises," where the student obtains interactive instruction as diagrammed in Fig. 4. The two examples given of this instruction, for a blood pressure monitor and for an infusion pump, show only a single sequence of instruction on the entire medical device. If

the student's interaction with the simulated or connected actual medical device is correct, the user will get a quiz and, if both are correct, the sequence will move on to the next part of the lesson. There is no apparent variation of the conditions under which the student's understanding is tested. There is only one condition for each control with one correct action. Hence there is no guidance given as to whether a particular interaction is appropriate under given conditions. Since these elements of Claim 1 are not found in Melker et al., it is respectfully submitted that Claim 1 and its dependent Claims 2-13 and 44-45 are not anticipated by Melker et al.

Claim 14 describes a system for providing instruction on the use of a medical device, the system comprising a) a network; b) a user computer coupled to the network for requesting instructional information on the use of the medical device; and c) a server coupled to the network; wherein the server provides a first graphical user interface having a list of instructional topics associated with the medical device to the user computer in response to the request for instruction, provides a second graphical user interface having a list of instructional sub-topics associated with an item on the list of instructional topics to the user computer in response to receiving a request for the item on the list of instructional topics from the user computer, provides a plurality of instructional graphical user interfaces having instructional information pertaining to an item on the list of instructional sub-topics to the user computer in response to receiving a request for the item on the list of the instructional sub-topics from the user computer, at least one of the first, second, and plurality of instructional graphical user interfaces

including at least one interactive simulation object with which interaction simulates operating controls or device instruments of the medical devices, and generates a feedback in response to interacting with the interactive simulation object indicating (i) whether a particular interaction is appropriate under given conditions; and (ii) the correctness on the use of the medical device. As previously described, Melker et al. have no list of instructional sub-topics associated with an item on the list of instructional topics whereby the student can obtain in-depth instruction on a specific sub-topic of interest to the student. Melker et al. contemplate only a single, overall course of study. As also discussed above, for each interaction Melker et al. only have one correct answer which, if given and optionally followed by correctly answering a quiz on the interaction, indicates the correctness (or incorrectness, in which case an educational lesson on the interaction is given) of the interaction and the program proceeds to the next section of the lesson. It is only correctness of the use of the device and the quiz answer which Melker et al. judge; they are unconcerned with indicating whether a particular interaction is appropriate under given conditions. For these reasons it is respectfully submitted that Claim 14 and its dependent Claims 15-25 and 46-47 are not anticipated by Melker et al.

Claim 38 describes a method for providing instruction on the use of a medical device to a user computer, the method comprising a) providing a medical device control object in a first graphical user interface, the medical device control object simulating a control of the medical device; b) providing a medical device first aid instrument object in the first graphical user interface or a second

graphical user interface, the medical device first aid object simulating a first aid component of the medical device; g) allowing a trainee to interact with the medical device control object and medical device first aid instrument object by manipulation of the displayed medical device control object and medical device first aid instrument object in the first or second graphical user interface; and c) providing feedback in response to interacting with the medical device control object and medical device first aid instrument object, the feedback indicating the correctness of the interaction with the medical device control object and the medical device first aid instrument object. An embodiment of this invention provides two types of training for a medical device: both its operation and its use with a patient. In the case of a defibrillator, for example, the first aid instrument object would be the electrode pads and the control object would be the defibrillator controls. The instruction method would teach the student on the proper operation of the defibrillator controls and on correct placement of the electrode pads on the patient, for instance. If the student would attempt to analyze the ECG or measure patient impedance before attaching the pads to the patient, the instructional program would alert the student that the intended analysis or measurement was incorrect because the electrode pads have to be attached to the patient before either analyzing the ECG or measuring patient impedance. Melker et al.'s interactive program examples in col. 7 concentrate on testing the student's use of controls for the functions of the device. It appears to be the earlier non-interactive parts of the program, the Instrument Operation and the Pathophysiology lessons, which deal with

instructing on the use of the device with patients. Accordingly there is nothing in Melker et al. comparable to manipulating both a medical device control object and a medical device first aid instrument, nor is there anything comparable to providing feedback in response to interacting with these two objects. For these reasons it is respectfully submitted that Claim 38 and its dependent Claims 39-43 are not anticipated by Melker et al.

Claims 6-7, 8-13, 20-22, 23-25, and 41-43 were rejected under 35 U.S.C. §103(a) as being unpatentable over Melker et al. in view of US Pat. 5,791,907 (Ramshaw et al.) As previously discussed, Ramshaw et al. describes an instructional video for a surgical procedure which pauses occasionally and presents the student with several instruments for the next step in the procedure. The student is expected to pick one. Picking the wrong one will elicit a hint to guide a second selection. When the correct instrument is chosen, the video continues to demonstrate the use of the instrument in the next step of the procedure. The instructional video is one continuous instruction of the surgical procedure; it does not have topics from which a sub-topic can be chosen from a list of sub-topics for an interactive lesson on a certain aspect of the procedure. Furthermore, there is no interaction with an interactive simulation object; the instrument selection is simply a multiple-choice quiz where the student is expected to pick one of the selections. Only the correctness of the selection is judged, not the appropriateness of an interaction under given conditions. There is further no interaction or feedback on interaction with both a medical device control object and a medical device first aid object. The student is simply asked to

select the correct instrument, then the video subsequently proceeds to illustrate its use in the surgical procedure. It is thus seen that Ramshaw et al. have the same deficiencies as Melker et al. with respect to Claims 1, 14, and 38. Accordingly it respectfully follows that the combination of these two references cannot render their dependent Claims 6-7, 8-13, 20-22, 23-25, and 41-43 unpatentable.

Claims 3 and 17 were rejected under 35 U.S.C. §103(a) as being unpatentable over Melker et al. These claims depend from Claims 1 and 14 which have previously been shown to be patentable over Melker et al. by virtue of the deficiencies of Melker et al. with respect to the elements of these claims. Accordingly it is respectfully submitted that Claims 3 and 17 are patentable over Melker et al. by reason of their dependency.

In view of the foregoing amendment and remarks it is respectfully submitted that the claim informalities noted by the Examiner have been cured, that Claims 1-2, 4-5, 14-16, 18-19, 38-40 and 44-47 are not anticipated by Melker et al. and that Claims 3, 6-7, 8-13, 17, 20-22, 23-25, and 41-43 are patentable over the combination of Melker et al. and Ramshaw et al. Accordingly it is respectfully requested that the rejection of Claims 1-2, 4-5, 14-16, 18-19, 38-40 and 44-47 under 35 U.S.C. §102(e) and of Claims 3, 6-7, 8-13, 17, 20-22, 23-25, and 41-43 under 35 U.S.C. 103(a) be withdrawn and the case passed on to issuance.

In the alternative it is respectfully requested that the appeal be reinstated so that applicants can proceed with their right of appeal.

Respectfully submitted,

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